

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:6390
ANSWERED ON:07.05.2003
SALE OF COMBINATION DRUGS
VINAY KUMAR SORAKE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether combination drugs are considered irrational and dangerous;
- (b) whether under Para 122(E) of the Drugs and Cosmetics Rules, whenever two or more drugs are combined to form a new drug, it requires the mandatory approval of the Drugs Controller of India;
- (c) whether a large number of such combination drugs are sold in India without the DCI's approval;
- (d) if so, the reasons therefor; and
- (e) the action taken against the erring companies selling combination drugs?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

- (a) No Sir, Combinations of drugs are based on valid therapeutic principles and patient compliance etc.
- (b) Under rule-122 E (c) of Drugs and Cosmetics Rules - a fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, requires prior approved from Drugs Controller (India).
- (c) & (d) The Drug manufacturing licences including patent and proprietary medicines are granted by State Licensing Authority under the provisions of Drugs and Cosmetics Rules. The said Rules have been amended through Gazette Notification No.GSR 311 (E) dated 1st May, 2002, making it mandatory for the State Licensing Authorities to ensure that drug formulations falling under the definition of new drug should have prior permission from Drugs Controller (India)
- (e) The concerned State Licensing Authorities are directed to withdraw permissions for such formulations.